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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,026	12/16/2004	Gary Mark Coppola	PC/4-32444A	4647

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
GRAZIER, NYEEMAH	
ART UNIT	**PAPER NUMBER**
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,026	COPPOLA ET AL.	
	Examiner	Art Unit	
	Nyeemah Grazier	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/13/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *16-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25* is/are rejected.

7)☒ Claim(s) *1-16 and 34-37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

First Action on the Merits

I. ACTION SUMMARY

Claims 1-27 are currently pending. Claims are withdrawn from further consideration by the Examiner because Claims 17-23 are drawn to a non-elected invention. 37 C.F.R. § 1.142(b).

II. PRIORITY

This application is a 371 of PCT/EP03/03466 filed on April 2, 2003 and claims priority to U.S. Provisional Applications 60/369,930 and 60/369,779 filed on April 3, 2002.

III. INFORMATION DISCLOSURE STATEMENT

The information disclosure statement (IDS) submitted on March 8, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

IV. RESTRICTION/ELECTION

A. Election: Applicant's Response

Applicant's election of Group I, claims 1-16 and 24-27, and provisional specie election of the compound of Example 43, in the response filed on November 13, 2006 is acknowledged.

The applicant has admitted that "prior art against one of the groups would not be prior art against any of the other groups." The applicant traverses the restriction on the grounds that the restriction is improper because the inventions are neither independent nor distinct

and therefore would not impose a burden on the Examiner. (See Remarks, p. 2, filed November 13, 2006).

This is not found persuasive because of the reasons set forth in the Lack of Unity of Invention Action. Furthermore the Markush group set forth in the claims includes both independent and distinct inventions and patentably distinct compounds. For example, in the instant invention, variable X and Y may each represent CH or nitrogen; or –X=Y- may represent sulfur, oxygen or NR14, for example. Thus, the products are distinct as indicated by the various classifications and subclassifications. For instance, pyridines are classified in class 546, while 1,2-diazines are classified in class 544. Additionally, because of the plethora of classes and subclasses in each of the Inventions, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Lack of restriction would impose a serious burden on the Examiner. Thus, based on the abovementioned rationale, the restriction as set forth in the instant application is proper.

In sum, Formula (I) have diverse chemical structures, different chemical properties, different modes of action, and different effects and reactive conditions and is therefore recognized in the art as being distinct from one another. MPEP §§ 806.04, 808.01. Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention, i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The rebuttable presumption, that similar chemical structures behave similarly, may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The requirement is still deemed proper and is therefore made FINAL.

The abovementioned argument regarding the restriction requirement between the compounds and method of use claims have been fully considered and is not persuasive. The inventions have been shown to be independent and distinct. As stated in the previous Action upon determining that the product claims are allowable, the method claims commensurate in scope with the allowable subject matter will be rejoined. (*See* Action filed July 13, 2006, Advisory of Rejoinder Section, p. 4).

B. Status of the Claims

i. Scope of the Elected Subject Matter

The scope of the elected subject matter ***has been broadened*** and are the compounds and compositions of formula (I) wherein:

X and **Y** are each –CH-,

Q2, L3, L1, L2, Z, Q1, R1 and **R2** have the *original full scope* set forth in the instant claims.

ii. Non-elected Subject Matter Withdrawn 37 C.F.R. §1.142(b)

The non-elected subject matter withdrawn under 37 CFR 1.142(b) are the compounds of Formula (I) wherein either **X** or **Y** or both **X** and **Y** represent nitrogen; or wherein **–X=Y-** represents sulfur, oxygen or –NR14-.

V. REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms "insulin derivative or mimetic, insulinotropic sulfonylurea receptor ligand receptor, DPP-IV inhibitor, etc. have not been sufficiently described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time of filing, were in possession of the claimed invention.

Claim 25 is also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using the composition, the Specification does not reasonably provide enablement for compositions comprising the compounds of claim 1 combined with *any* DDP-IV or insulin derivative, for example. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use or make the invention commensurate in scope with these claims.

The relevant factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph have been set forth in *In re* Wands. See *In re* Wands, 8 USPQ.2d 1400 (1988). The factors are as follows:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The relevant factors: lack of predictability in the art, amount of direction and guidance provided by the inventor, existence of working examples, breadth of claims and quantity of experimentation needed to make or use the invention based on the Specification; have been individually set forth below.

Level of Predictability in the Art:

Because of high level of unpredictability associated with the use of pharmaceutical compositions for the treatment of vast diseases, a greater amount of evidentiary support is needed to satisfy the requirement of 35 U.S.C 112, first paragraph. The pharmacology may require screening in vitro and in vivo studies to determine and identify a specific compound that show the desired pharmacological efficacy and the mechanism thereof. In the instant invention, the level of predictability is high because the invention is drawn to the compound of claim 1 in combination with other classes of compounds that have not been disclosed.

The Amount of Direction or Guidance Present

The claims are drawn to a pharmaceutical composition comprising the compounds of claim 1 and therapeutically effective amount of other compounds without limitation . Thus, there is limited guidance and therefore the specification does not enable the public to prepare such compositions. For example, the claim reads on any DPP-IV inhibitor or insulin mimetic.

The Presence or Absence of Working Examples

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will posses the alleged activity. See *In re* Riat (CCPA 1964) 327 F2d 685, 140USPQ 471; *In re* Barr (CCPA 1971) 444 F 2d 349, 151 USPQ 724. The instant Specification provides an

exemplary list of a few therapeutic agents. These agent should be incorporated into the claim. See, e.g. p. 36-37.

The Breadth of the Claims

The instant rejected claim is extremely broad because of the vast number of possible compositions which comprise the compound of claim 1 and endless therapeutic agents.

The Quantity of Experimentation Needed

Based on the unpredictable nature of the invention and the state of the prior art and the breadth of the claims, one of ordinary skill in the art would be burdened with undue "experimentation study" to determine the claimed composition. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ.2d 1001 (stating that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable").

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to determine the scope of the composition envisioned.

VI. OBJECTION(S)

Recitation of an intended use or utility in the preamble which can otherwise stand alone is not considered a further limitation of the claim and therefore cannot impart patentability to a known composition of matter. See, In re Spada, 15 USPQ.2d 1655 (Fed. Cir. 1990).

Claims 26 and 27 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim24. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper

after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 1-5, 7, 8, and 16 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should amend the claims by deleting the non-elected subject matter.

Claims 2-16 and 24-27 are objected to as depending from a rejected based or objected claim.

VII. CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,

KAMAL A. SAEED, PH.D.
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